

Amendments to the Specification

Please replace paragraph [0083] with the following paragraph:

EXAMPLE 3

*Particle Size, Particle Density, and Rate of Inhalable Particle Formation of
Diphenhydramine Aerosol*

[0083] A solution of 15.5 mg diphenhydramine in 200 μ L dichloromethane was spread out in a thin layer on the central portion of a 4 cm x 9 cm sheet of aluminum foil. The dichloromethane was allowed to evaporate. Assuming a drug density of about 1g/cc, the calculated thickness of the diphenhydramine thin layer on the 36 cm² aluminum solid support, after solvent evaporation, is about 4.3 microns. The aluminum foil was wrapped around a 300 watt halogen tube, which was inserted into a T-shaped glass tube. One of the openings of the tube was sealed with a rubber stopper, another was loosely covered with the end of the halogen tube, and the third was connected to a 1 liter, 3-neck glass flask. The glass flask was further connected to a large piston capable of drawing 1.1 liters of air through the flask. Alternating current was run through the halogen bulb by application of 60 V using a variac connected to 110 V line power. Within 1 s, an aerosol appeared and was drawn into the 1 L flask by use of the piston, with collection of the aerosol terminated after 10 s. The aerosol was analyzed by connecting the 1 L flask to an eight-stage Andersen non-viable cascade impactor. Results are shown in table 1. MMAD of the collected aerosol was 1.2 microns with a geometric standard deviation of 2.2. Also shown in table 1 is the number of particles collected on the various stages of the cascade impactor, given by the mass collected on the stage divided by the mass of a typical particle trapped on that stage. The mass of a single particle of diameter D is given by the volume of the particle, $\pi D^3/6$, multiplied by the density of the drug (taken to be 1 g/cm³). The inhalable aerosol particle density is the sum of the numbers of particles collected on impactor stages 3 to 8 divided by the collection volume of 1 L, giving an inhalable aerosol particle density of 6×10^7 particles/mL. The rate of inhalable aerosol particle formation is the sum of the numbers of particles collected on impactor stages 3 through 8 divided by the formation time of 10 s, giving a rate of inhalable aerosol particle formation of 6×10^9 particles/second.

Table 1: Determination of the characteristics of a diphenhydramine condensation aerosol by cascade impaction using an Andersen 8-stage non-viable cascade impactor run at 1 cubic foot per minute air flow.

Stage	Particle size range (microns)	Average particle size (microns)	Mass collected (mg)	Number of particles
0	9.0-10.0	9.5	0.0	0

1	5.8-9.0	7.4	0.0	0
2	4.7-5.8	5.25	0.1	1.3×10^6
3	3.3-4.7	4.0	0.3	9.0×10^6
4	2.1-3.3	2.7	0.5	4.9×10^7
5	1.1-2.1	1.6	1.4	6.5×10^8
6	0.7-1.1	0.9	1.0	2.6×10^9
7	0.4-0.7	0.55	0.5	7.6×10^9
8	0-0.4	0.2	0.2	4.8×10^{10}